

TRANSMITTAL FORM

EXPRESS MAIL NO.: EL953456281US

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| Application Serial Number | 10/045,360 |
| Filing Date | January 22, 2002 |
| First Named Inventor | Whitehead |
| Group Art Unit | Not yet assigned |
| Examiner Name | Not yet assigned |
| Attorney Docket No. | UPA-008 |
| BATCH NO. (after allowance) | Not applicable |
| Patent No. | Not applicable |
| Issue Date | Not applicable |

ENCLOSURES (check all that apply)

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| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553) | <input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences |
| <input type="checkbox"/> Amendment and Response <input type="checkbox"/> Preliminary Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____] | <input type="checkbox"/> Formal Drawing(s) | <input type="checkbox"/> Appeal Brief (in triplicate) |
| <input type="checkbox"/> Petition for Extension of Time | <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal | <input type="checkbox"/> Status Inquiry |
| <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations | <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) | <input checked="" type="checkbox"/> Return Receipt Postcard |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> Terminal Disclaimer | <input type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 |
| <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above | <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application | <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8 |
| | <input type="checkbox"/> Small Entity Statement | <input type="checkbox"/> Additional Enclosure(s) (please identify below) |
| | <input type="checkbox"/> CD(s) for large table or computer program | |
| | <input type="checkbox"/> Amendment After Allowance | |
| | <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate) | |

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Respectfully submitted,

Date: March 14, 2002
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EXPRESS MAIL MAILING LABEL NO.: EL953456281US

PATENT

Attorney Docket No: UPA-008
(8261/9)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Whitehead
SERIAL NO.: 10/045,360 GROUP NO.: Not yet assigned
FILED: January 22, 2002 EXAMINER: Not yet assigned
TITLE: METHODS FOR DETERMINING STEROID RESPONSIVENESS

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

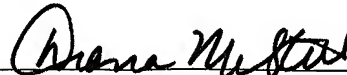
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,



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| FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT | | | | ATTORNEY DOCKET NO.: UPA-008 APPLICANT: Whitehead SERIAL NO.: 10/045,360 FILING DATE: January 22, 2002 GROUP: Not yet assigned | | | | | |
| U.S. PATENT DOCUMENTS | | | | | | | | | |
| EXAM. INIT. | | DOCUMENT NUMBER | DATE | NAME | | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
| EXAM. INIT. | | DOCUMENT NUMBER | DATE | COUNTRY CODE | CLASS | SUB CLASS | FILING DATE | ABSTRACT ONLY | ENGLISH LANG (Y/N) |
| | | | | | | | | | |
| OTHER ART, JOURNAL ARTICLES, ETC. | | | | | | | | | |
| EXAM. INIT. | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) | | | | | | | | |
| | C1 | Butler et al., "Structure of the Mouse Serum Amyloid A 5 (SAA5) Gene: Relationship to Other Members of the Serum Amyloid A Family", Scand. J. Immunol., Vol. 45, pp. 160-165, 1997. | | | | | | | |
| | C2 | Butler et al., "Mapping of the Mouse Serum Amyloid A Gene Cluster by Long-Range Polymerase Chain Reaction", Immunogenetics, Vol. 44, pp. 468-474, 1996. | | | | | | | |
| | C3 | Cohen et al., "Therapy of Relapsing Multiple Sclerosis. Treatment Approaches for Nonresponders", J. Neuroimmunol., Vol. 98, pp. 29-36, 1999. | | | | | | | |
| | C4 | Cunnane et al., "Amyloid Precursors and Amyloidosis in Rheumatoid Arthritis", Baillière's Clinical Rheumatol., Vol. 13, No. 4, pp. 615-628, 1999. | | | | | | | |
| | C5 | Cunnane et al., "Serum Amyloid A in the Assessment of Early Inflammatory Arthritis", Rheumatol., 27:1, 2000. | | | | | | | |
| | C6 | Gaughan et al., "Ribozyme Mediated Cleavage of Acute Phase Serum Amyloid A (A-SAA) mRNA in Vitro", FEBS Letters, 374, pp. 241-245, 1995. | | | | | | | |
| | C7 | Gaughan et al., "Efficient In Vitro Cleavage of Mouse Acute Phase Serum Amyloid A mRNA Mediated by a Synthetic Hammerhead Ribozyme", Scand. J. Immunol., Vol. 46, pp. 51-58, 1997. | | | | | | | |
| | C8 | Grehan et al., "Expression of a Biologically Active Recombinant Mouse IL-1 Receptor Antagonist and its Use in Vivo to Modulate Aspects of the Acute Phase Response", J. Immunol., pp. 369-378, 1997. | | | | | | | |
| | C9 | Grehan et al., "Down-Regulation of the Major Circulating Precursors of Proteins Deposited in Secondary Amyloidosis by a Recombinant Mouse Interleukin-1 Receptor Antagonist", Eur. J. Immunol., Vol. 27, pp. 2593-2599, 1997. | | | | | | | |



FORM PTO - 1449

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: UPA-008


APPLICANT: Whitehead

SERIAL NO.: 10/045,360

FILING DATE: January 22, 2002

GROUP: Not yet assigned

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| C10 | Hanauer et al., "Management of Crohn's Disease in Adults", Amer. J. Gastroenter., Vol. 92, No. 4, 1997. |
| C11 | Hendrickse et al., "Rifampicin-Induced Non-Responsiveness to Corticosteroid Treatment in Nephrotic Syndrome", Brit. Med. J., p. 306, February 3, 1979. |
| C12 | Jain et al., "Rifampicin Induced Non-Responsiveness to Steroids in Bronchial Asthma", Indian. J. Chest. Dis. & All Sci., Vol. 31, No. 4, pp. 271-274, 1989. |
| C13 | Jensen et al., "Competitive Reverse Transcription Polymerase Chain Reaction for Quantifying Pre-mRNA and mRNA of Major Acute Phase Proteins", J. Immunol. Meth., Vol. 215, pp. 45-48, 1998. |
| C14 | Jensen et al., "Review Article - Regulation of Serum Amyloid A Protein Expression During the Acute-Phase Response", Biochem. J., Vol. 334, pp. 489-503, 1998. |
| C15 | Jensen et al., "Evolutionary Analyses and Acute Phase Response", J. Immunol., pp. 384-392, 1997. |
| C16 | Jorgensen et al., "Serum Amyloid A Transcription in Atlantic Salmon (<i>Salmo salar</i> L.) Hepatocytes is enhanced by Stimulation with Macrophage Factors, Recombinant Human IL-1 β , IL-6 and TNF α or bacterial lipopolysaccharide", Devel. and Compar. Immunol., Vol. 24, pp. 553-563, 2000. |
| C17 | Kornbluth et al., "Ulcerative Colitis Practice Guidelines in Adults", Am. J. of Gastroent., Vol. 92, No. 2, 1997. |
| C18 | Longley et al., "Posttranscriptional Regulation of Acute Phase Serum Amyloid A2 Expression by the 5'- and 3' - Untranslated Regions of Its mRNA", J. Immunol., pp. 4538-4545, 1999. |
| C19 | McCormack et al., "Generation of Soluble Recombinant Human Acute Phase Serum Amyloid A2 (A-SAA2) Protein and its Use in Development of a A-SAA Specific ELISA", J. Immunol. Meth., Vol. 198, pp. 101-110, 1996. |
| C20 | O'Hara et al., "Acute-Phase Serum Amyloid A Production by Rheumatoid Arthritis Synovial Tissue", Arthritis Res. Vol. 2, pp. 142-144, 2000. |
| C21 | O'Mahony et al., "Review Article: Management of Patients with Non-Responsive Coeliac Disease", Aliment Pharmacol. Ther., Vol. 10, pp. 671-68, 1996. |
| C22 | Present, "How To Do Without Steroids in Inflammatory Bowel Disease", Inflamm. Bowel Dis., Vol. 6, No. 1, February 2000. |
| C23 | Rebuck, "Asthma: Non-Responsiveness to Conventional Therapy", Eur. J. Respir. Dis., 69 (Suppl. 147), pp. 105-109, 1986. |
| C24 | Rygg et al., "In Vitro Evaluation of an Enhanced Human Serum Amyloid A (SAA2) Promoter-Regulated Soluble TNF Receptor Fusion Protein for Anti-Inflammatory Gene Therapy", Scand. J. Immunol., Vol. 53, pp. 588-595, 2001. |
| C25 | Spitz et al., "Response to the Antiprogesterone RU 486 (mifepristone) During Early Pregnancy and the Menstrual Cycle in Women", J. Reprod. Fert., Suppl., Vol. 37, pp. 253-260, 1989. |

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| | C26 | Steel et al., "Expression and Regulation of Constitutive and Acute Phase Serum Amyloid A mRNAs in Hepatic and Non-Hepatic Cell Lines", Scand. J. Immunol., Vol. 44, pp. 493-500, 1996. | |
| | C27 | Uhlar et al., "Wallaby Serum Amyloid A Protein: cDNA Cloning, Sequence and Evolutionary Analysis", Scand. J. Immunol., Vol. 43, pp. 271-276, 1996. | |
| | C28 | Uhlar et al., "The Kinetics and Magnitude of the Synergistic Activation of the Serum Amyloid A Promoter by IL-1 β and IL-6 is Determined by the Order of Cytokine Addition", Scand. J. Immunol., Vol. 49, pp. 399-404, 1999. | |
| | C29 | Uhlar et al., "Use of the Acute Phase Serum Amyloid A2 (SAA2) Gene Promoter in the Analysis of Pro- and Anti-Inflammatory Mediators: Differential Kinetics of SAA2 Promoter Induction by IL-1 β and TNF- α compared to IL-6", J. Immunol. Meth., Vol. 203, pp. 123-130, 1997. | |
| | C30 | Uhlar et al., "Review Article - Serum Amyloid A, the Major Vertebrate Acute-Phase Reactant", Eur. J. Biochem., Vol. 265, pp. 501-523, 1999. | |
| EXAMINER | | DATE CONSIDERED | |

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